



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 12/8/97

SUBJECT: ID#98FL0002. SECTION 18 EXEMPTION FOR THE USE OF
MYCLOBUTANIL ON STRAWBERRIES IN FLORIDA.

DP Barcode: D240324

PRAT Case#: 289315

Submission #: S531823

Caswell#: 723K

Chemical#: 128857

Class: Fungicide

Trade Name: NOVA 40W

40 CFR: 180.443

EPA Reg#: 707-221

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MJIERB/RD (7505C)

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INTRODUCTION

The Florida Department of Agriculture and Consumer Services is proposing a specific exemption for the use of myclobutanil on strawberries for control of powdery mildew (Sphaerotheca macularis). This is the sixth §18 request for this use. The proposed program will entail application of 11,250 lbs of NOVA 40W [4,500 lbs ai] on 6,000 acres statewide from March 31, 1998 to March 31, 1999.

SUMMARY

The following restriction should be added to the label for the requested Section 18 on strawberries: Myclobutanil treated fields can be rotated at any time to crops which are included on a myclobutanil label. All other crops may be planted one year following applications of myclobutanil.

Occupational exposure and aggregate risk estimates do not exceed HED's level of concern. This Section 18 exemption should not pose an unacceptable aggregate risk to infants, children, or adults. Therefore, **provided the above statement regarding rotational crops is added to the label**, HED has no objection to the issuance of this Section 18 exemption for the use of myclobutanil on strawberries in the State of Florida. A time-limited tolerance for residues of myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) in/on strawberries at 0.5 ppm should be established to support this Section 18 exemption.

NOTES:

- 1) The submitted Section 18 label states that a maximum of 0.75 lb ai/A/crop (30 ozs product/A/crop) may be applied. This should be modified to state that a maximum of 0.75 lb ai/A/year (30 ozs product/A/year) can be applied.
- 2) RD should insure that the appropriate REI statement appears on the label.

TOXICOLOGICAL ENDPOINTS

DIETARY

- 1) *Acute Toxicity.* None. For acute dietary risk assessment, the Hazard ID Assessment Review Committee (HAZID SARC) did not recommend an acute dietary endpoint.
- 2) *Chronic Toxicity.* RfD = 0.025 mg/kg/day. The RfD is currently established to be 0.025 mg/kg/day based on the NOEL from the chronic feeding study in the rat (2.49 mg/kg/day; MRID #00165247) and a safety factor of 100 [10 for

intraspecies and 10 for interspecies]. The LOEL for the chronic rat feeding study is 9.84 mg/kg/day based on decreased testicular weight and increased testicular atrophy. The HAZID SARC noted that the dose of 2.49 mg/kg/day established in the above study is supported by the Parental Systemic Toxicity NOEL and LOEL established in the Two-Generation reproduction study in rats. In that study the NOEL was 2.5 mg/kg/day and the LOEL was 10 mg/kg/day. The Committee determined that the 10 x factor to account for enhanced sensitivity of infants and children (as required by FQPA) should be removed. A UF of 100 is adequate because of the following:

(i) Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits.

(ii) A two generation reproduction toxicity study in rats showed no increased sensitivity in pups that were compared to adults.

(iii) The toxicology data base is complete and there are no data gaps.

The Joint Meeting on Pesticide Residues (JMPR) established an ADI (RFD) of 0.03 mg/kg/day.

NON-DIETARY

- 1) *Short-Term Toxicity.* For short-term Margin of Exposure (MOE) calculations, the HAZID SARC recommended use of the systemic NOEL of 100 mg/kg/day [HDT] from the 28-day dermal toxicity study in rats (MRID# 266080). There was no LEL in the study.
- 2) *Intermediate-Term Toxicity.* For intermediate-term MOE calculations, the HAZID SARC recommended use of the reproductive NOEL of 10 mg/kg/day based on atrophy of the testes and prostate as well as an increase in the number of stillborns and a decrease in pup weight gain during lactation at the LOEL of 50 mg/kg/day (LOEL) from the 2-generation reproduction study in rats (MRID# 00143766, 00149581).

- 3) *Chronic Toxicity.* The HAZID SARC determined that a chronic toxicity endpoint and risk assessment for myclobutanil is not required for workers.
- 4) *Dermal Penetration.* For short-term MOE calculations, a dermal toxicity study was used, so dermal penetration data were not required. The HAZID SARC determined that a dermal absorption factor of 100% should be used for risk assessment because 1) a dermal absorption study was not available with the technical and 2) a dermal absorption factor could not be estimated due to the lack of comparative NOELs/LOELs from oral and dermal toxicity studies in the same species with the technical. The dermal absorption factor is required for Intermediate and Long-Term dermal risk assessment since oral doses were selected for these exposure periods. Dermal absorption is not required for Short-Term dermal exposure risk assessment since a dermal dose from a 28-day dermal toxicity study was selected for this time period.

CANCER

Myclobutanil is classified as Category E: not carcinogenic in two acceptable animal studies. Q_1^* is not applicable.

EXPOSURES AND RISKS

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor and/or outdoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. From Food and Feed Uses:

Tolerances have been established (40 CFR 180.443) for the residues of myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-

propanenitrile (free and bound), expressed as myclobutanil, in or on a variety of raw agricultural commodities and processed commodities at levels ranging from 0.02 ppm in cottonseed to 25.0 ppm in raisin waste. Meat, milk, poultry and egg tolerances have been established at levels ranging from 0.02 ppm to 1.0 ppm.

Acute Risk. The HAZID SARC did not recommend an acute dietary toxicological endpoint so an acute dietary risk assessment is not required (10/21/97 meeting).

Chronic Risk. In conducting this chronic dietary (food only) risk assessment, HED has made somewhat conservative assumptions. With the exceptions of bananas for which a level representing residues in pulp rather than the whole banana was used and selected commodities which were corrected for percent crop treated, all commodities having myclobutanil tolerances will contain myclobutanil and metabolite residues and those residues will be at the level of the established tolerance. This results in an overestimate of human dietary exposure. For bananas, the level of 0.8 ppm was used in the dietary risk assessment rather than the proposed tolerance of 4.0 ppm on bananas since residues in the pulp will not exceed 0.8 ppm. Percent crop-treated estimates were utilized for selected commodities included in the assessment. Thus, in making a safety determination for this tolerance, EPA is taking into account this partially refined exposure assessment.

The existing myclobutanil tolerances (published, pending, and including the necessary Section 18 tolerances) for crops other than bananas and the anticipated residues on bananas result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

<u>Population Subgroup</u>	<u>ARC_{food} (mg/kg/day)</u>	<u>%RfD</u>
U.S. Population (48 states)	0.004255	17%
Nursing Infants (<1 year old)	0.006359	25%
Non-Nursing Infants (<1 year old)	0.018836	75%
Children (1-6 years old)	0.011492	46%
Children (7-12 years old)	0.006910	28%
Northeast Region	0.004539	18%
Western Region	0.004848	19%
Hispanics	0.005049	20%
Non-Hispanic Others	0.004425	18%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. From Drinking Water:

Based on information in the EFED One Liner Database (updated: 12/20/94), myclobutanil is persistent and not considered mobile in soils with the exception of sandy soils. Data are not available for its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile. There is no established Maximum Contaminant Level for residues of myclobutanil in drinking water (Safe Drinking Water Hotline - personal communication 5/14/97). No Health Advisory Levels for myclobutanil in drinking water have been established. The "Pesticides in Groundwater Database" (EPA 734-12-92-001, September 1992) has no information concerning myclobutanil.

The Environmental Fate and Effects Division (D239591, Douglas Urban, 11/4/97) has provided estimates of ground and surface water concentrations for myclobutanil based on the label rate of 0.65 lbs a.i./acre and assuming 15 applications per season. (The water numbers were based on turf.) The surface water numbers are based on the results of GENEEC model run. The ground water numbers are based on a screening tool, SCI-GROW, which tends to overestimate the true concentrations in the environment.

Surface water EEC [based on the results of a GENEEC
(Version 1.2, 5/3/95) model run]

Acute = 145.96 ppb (0.14596 ppm or mg/L) (maximum initial concentration)

Chronic = 118.6 ppb (0.1186 ppm or mg/L) (average 56-day concentration)

Note: OPP policy allows the 90/56-day GENEEC value to be divided by 3 to obtain a value for chronic risk assessment calculations. Therefore, the surface water value for use in the chronic risk assessment would be 0.04 ppm or mg/L.

Ground water EEC (SCI-GROW, Lotus 1-2-3 spreadsheet)

3.6 ppb (0.0036 ppm or mg/L) (use for both acute and chronic)

Chronic exposure from surface water is calculated below. Chronic exposure from ground water is lower.

Note: Exposure (mg/kg/day) = concentration in water in mg/L x 2 L water/day for males or females or 1 L water/day for children ÷ 70 kg for adult males or 60 kg for adult females or 10 kg for children

chronic exposure from surface water for adult males =
 $0.04 \text{ mg/L} \times 2 \text{ L/day} \div 70 \text{ kg} = 1.1 \times 10^{-3} \text{ mg/kg/day}$

chronic exposure from surface water for adult females =
 $0.04 \text{ mg/L} \times 2 \text{ L/day} \div 60 \text{ kg} = 1.3 \times 10^{-3} \text{ mg/kg/day}$

chronic exposure from surface water for children =
 $0.04 \text{ mg/L} \times 1 \text{ L/day} \div 10 \text{ kg} = 4.0 \times 10^{-3} \text{ mg/kg/day}$

3. From Non-Dietary Uses:

Myclobutanil is currently registered for outdoor residential and greenhouse use on annuals and perennials, turf, shrubs, trees, and flowers (Reference Files System/OPP LAN, date searched: 6/5/97). HED has determined that these uses do not constitute a chronic exposure scenario, but may constitute a short- to intermediate-term exposure scenario.

Homeowner-use Products

End-use products containing the active ingredient, myclobutanil, are marketed for homeowner use. The homeowner use with the greatest potential for exposure takes the form of small scale lawn application of the granular formulation with a handheld or push-type spreader or the application of a soluble concentrate with a hose-end or trigger bottle sprayer. Application of these products is recommended at two week intervals. Both short-term and intermediate-term exposure is considered.

Handler Exposures and Assumptions

HED has determined that there is potential for exposures to applicators and handlers during usual homeowner use-patterns associated with myclobutanil. Based on the use patterns, three exposure scenarios with the greatest potential for exposure are considered: 1) loading and application of granular product by hand held rotary granular spreader; 2) loading and application of a soluble concentrate product by low pressure handwand sprayer; and 3) loading and application of a soluble concentrate product by garden hose end sprayer.

Short-term and intermediate-term dermal exposure assessments using the Pesticide Handlers Exposure Database (PHED) Version 1.1 surrogate data and baseline risk calculations for homeowners are presented in Table 1. Table 2 summarizes the caveats (e.g., data confidence) and parameters specific to each exposure scenario and corresponding risk assessment.

TABLE 1. Baseline Short-Term and Intermediate-Term Exposure and Risk Assessments for Homeowner Use of Myclobutanil

Exposure Scenario	Baseline Dermal + Inhalation Unit Exposure (mg/lb ai) ^a	Maximum Application Rate (lb ai/acre) ^b	Maximum Acres/Day ^c	Total Daily Exposure (mg ai/day) ^d	Total Daily Dose (mg ai/kg/day) ^e		Short-Term MOE ^f	Intermediate-Term MOE ^f
					BW= 70 kg	BW= 60 kg		
1. Load/Apply Granular Using Handheld Rotary Spreader	3.01	1.0* This rate is assumed since label provided was incomplete.	0.46	1.38	0.02	0.02	5000	500
2. Load/Apply Soluble Concentrate Using Low Pressure Handwand	103.60	0.95	0.46	45.3	0.65	0.75	160	13
3. Load/Apply Soluble Concentrate Using Garden Hose End Sprayer	30.20	0.95	0.46	13.2	0.19	0.22	530	45

- a Baseline unit exposure (dermal + inhalation), taken from PHED Version 1.1 data in the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments dated July 18, 1997, represents short pants, short sleeve shirt, no gloves, and open loading. Note that for some PHED data correction factors were applied to arrive at the baseline scenario.
- b Application rate comes from maximum rates found on the Myclobutanil labels.
- c Daily acres treated values are from Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments dated July 18, 1997, estimates of acreage that could be treated in a single day for each exposure scenario of concern.
- d Total Daily Exposure (mg ai/day) = Unit exposure (mg/lb ai) x Application Rate (lbs ai/acre) x Acres Treated.
- e Total Daily Dose (mg/kg/day) = Daily Exposure (mg/day)/body weight (BW kg)
- f Margin of Exposure (MOE) = NOEL (mg/kg/day)/Daily Dermal Dose (mg/kg/day)

Table 2. Exposure Scenario Descriptions for Selected Residential Uses of Myclobutanil

Exposure Scenario (Number)	Data Source	Standard Assumptions	Comments
Mixer/Loader/Applicator Descriptors			
Load/Apply Granular Using Handheld Rotary Spreader (1)	PHED V1.1	0.46 Acres	Baseline: Medium confidence (23 replicates of ABC grade data) for dermal exposure. High confidence (40 replicates of AB grade data) for inhalation.
Load/Apply Soluble Concentrate Using Low Pressure Handwand (2)	PHED V1.1	0.46 Acres	Baseline: Low confidence (8-9 replicates of ABC grade data) for dermal exposure. Medium confidence (80 replicates of ABC grade data) for inhalation.
Load/Apply Soluble Concentrate Using Garden Hose End Sprayer (3)	PHED V1.1	0.46 Acres	Baseline: Low confidence (8 replicates of C and E grade data) for dermal exposure. Low confidence (8 replicates of C grade data) for inhalation. Based on one study.

^a Standard Assumptions based on Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments dated July 18, 1997. Baseline dermal exposure is based on the worker wearing short pants, short sleeve shirt, and no gloves.

Formulas for determining dermal exposure and risk to handlers are as follows:

- ▶ $\text{Daily Exposure (mg ai/day)} = \text{Unit Exposure (mg ai/lb ai)} \times \text{Use Rate (lb ai/acre)} \times \text{Maximum Area Treated (acres/day)}$
- ▶ $\text{Daily Dermal Dose (mg ai/kg bw/day)} = \frac{\text{Daily Exposure (mg ai/day)}}{\text{Body Weight (kg)}}$
- ▶ $\text{Margin of Exposure (MOE)} = \frac{\text{NOEL (mg/kg/day)}}{\text{Daily Dermal Dose (mg/kg/day)}}$

The following are important assumptions used in the residential exposure assessments:

- For the short-term exposure assume exposed person's body weight is 70 kg; For the intermediate-term exposure assume exposed person's body weight is 60 kg; For the toddler (age 3) assume exposed body weight is 15 kg;
- Footnotes for Table 1 include other assumptions.

Homeowner Post-Application Exposures and Assumptions

The potential for post-application homeowner exposure exists. For example, potential exposures would be expected following applications to lawns and ornamental gardens sites. There are no chemical-specific data to use in assessing these potential exposures; therefore, a range finder post-application exposure and risk assessment was performed (Table 3). The assessment uses typical transfer coefficients (Tc) for low crops and/or low exposure activities (1,000 cm²/hr) and for high crops and/or high exposure activities (10,000 cm²/hr) and dislodgeable foliar residues (DFR) derived from the application rate and an estimated 20 percent of rate available as dislodgeable. EPA believes that exposures following soluble concentrate applications with a low pressure handwand to plants, such as lawn-turfgrass, are likely to represent a reasonably conservative post-application exposure estimate to homeowners and children. **Chemical-specific dissipation data and residential use/usage information is required to further refine these post-application exposure estimates.**

Table 3. Surrogate Postapplication Range-Finder Assessment.

DAT ^a	Surrogate DFR ($\mu\text{g}/\text{cm}^2$) ^b	Dermal Dose (mg/kg/day) ^c			Adult Short- Term MOE ^d	Toddler Short- Term MOE ^d	Adult Intermedi- ate-Term MOE ^d	Toddler Intermedi- ate-Term MOE ^d
		BW = 70 kg	BW = 60 kg	BW = 15 kg				
Low Exposure Activities (Tc = 1,000 cm ² /hr)*								
0.00	2.24	0.064	0.075	0.30	1600	330	130	33
High Exposure Activities (Tc = 10,000 cm ² /hr) ^f								
0.00	2.24	0.64	0.75	3.0	160	33	13	3

a DAT is days after treatment based on an application rate of 1.0 lb ai/acre.

b Surrogate DFR ($\mu\text{g}/\text{cm}^2$) = Rate (lb ai/A) \times [(11.2 $\mu\text{g}/\text{cm}^2$)/(1 lb ai/A) conversion factor] \times percent (20 percent assumed) of rate available as dislodgeable

c Dermal Dose (mg/kg/day) = [DFR ($\mu\text{g}/\text{cm}^2$) \times Tc (cm²/hr) \times (1 mg/1,000 μg unit conversion) \times 2 hours/day] / Body Weight (BW kg)

d MOE = NOEL (mg/kg/day)/Dermal Dose (mg/kg/day)

e Low exposure crops include low-growing ornamentals and established turf.

f High exposure crops include ornamental trees, plants, and shrubs.

4. From Cumulative Exposure To Substances with a Common Mechanism of Toxicity:

Myclobutanil is a member of the triazole class of systemic fungicides (The Pesticide Book, 4th ed., 1994). Other triazoles include bitertanol, cyproconazole, diclobutrazole, difenoconazole, diniconazole, fenbuconazole, flusilazole, hexaconazole, penconazole, propiconazole, tebuconazole, tetraconazole, triadimefon, and triadimenol.

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot

process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

HED does not have, at this time, available data to determine whether myclobutanil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, HED has not assumed that myclobutanil has a common mechanism of toxicity with other substances.

DETERMINATION OF SAFETY FOR U.S. POPULATION

1. *Acute Aggregate Risk.* This risk assessment is not required as the HAZID SARC did not identify any acute dietary risk endpoints.

2. *Chronic Aggregate Risk.* Chronic Aggregate Exposure and Risk. Using the partially refined exposure assumptions described above, HED has concluded that aggregate exposure (food, water, and residential) to myclobutanil will not exceed HED's level of concern. The percent of the RfD that will be used by the food, water, and residential exposure for males (20 years and older) is 15% (i.e., 10.6% from food + 4.4% from water). The percent of the RfD that will be used by the food and water exposure for females

(20 years and older, not pregnant or nursing) is 15% (i.e., 10.1% from food + 5.2% from water). HED generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. HED has determined that the outdoor registered uses of myclobutanil would not fall under a chronic exposure scenario. HED concludes that there is a reasonable certainty that no harm will result from aggregate chronic exposure to myclobutanil residues.

3. *Short- and Intermediate-Term Aggregate Risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses. Although short-term exposure scenarios may be present, based on the lack of acute toxicological endpoints and the low percent of RfD occupied, in the best scientific judgement of HED, aggregate short- and intermediate-term risk will not exceed HED's level of concern. Additionally, HED notes that there are no indoor residential uses of myclobutanil; thus, indoor residential exposure is expected to be minimal.

DETERMINATION OF CANCER RISK

A cancer risk assessment is not needed since myclobutanil is classified as Category E: not carcinogenic in two acceptable animal studies.

ENDOCRINE DISRUPTER EFFECTS

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

Based on the adverse testicular findings in the chronic toxicity and reproduction studies in rats, myclobutanil should be considered as a candidate for evaluation as an endocrine disruptor.

DETERMINATION OF SAFETY FOR INFANTS AND CHILDREN

In assessing the potential for additional sensitivity of infants and children to residues of myclobutanil, HED considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproductive toxicity study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing fetus resulting from maternal pesticide exposure during gestation. Reproductive toxicity studies provide information relating to pre- and post-natal effects from exposure to the pesticide, information on the reproductive capability of mating animals, and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty (safety) factor/margin of exposure (safety) is designed to account for inter-species extrapolation and intra-species variability. HED believes that reliable data support using the 100-fold margin/factor, rather than the 1000-fold margin/factor, when EPA has a complete data base under existing guidelines, and when the severity of the effect in infants or children, the potency or unusual toxic properties of a compound, or the quality of the exposure data do not raise concerns regarding the adequacy of the standard margin/factor.

1. Developmental Toxicity Studies.

a. Rats. In the developmental study (MRID# 00141672) in rats, the maternal (systemic) NOEL was 93.8 mg/kg/day, based on rough hair

coat, and salivation at the LOEL of 312.6 mg/kg/day. The developmental (fetal) NOEL was 93.8 mg/kg/day based on incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day.

b. Rabbits. In the developmental toxicity study (MRID# 00164971) in rabbits, the maternal (systemic) NOEL was 60 mg/kg/day, based on reduced weight gain, clinical signs of toxicity and abortions at the LOEL of 200 mg/kg/day. The developmental (fetal) NOEL was 60 mg/kg/day, based on increases in number of resorptions, decreases in litter size, and a decrease in the viability index at the LOEL of 200 mg/kg/day.

2. Reproductive Toxicity Studies.

Rats. In the 2-generation reproductive toxicity study (MRID# 00143766, 00149581) in rats, the parental (systemic) NOEL was 2.5 mg/kg/day, based on increased liver weights and liver cell hypertrophy at the LOEL of 10 mg/kg/day. The developmental (pup) NOEL was 10 mg/kg/day, based on decreased pup body weight during lactation at the LOEL of 50 mg/kg/day. The reproductive (pup) NOEL was 10 mg/kg/day, based on the increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

3. Pre- and Post-Natal Sensitivity.

The pre- and post-natal toxicology data base for myclobutanil is complete with respect to current toxicological data requirements. Based on the developmental and reproductive toxicity studies discussed above, for myclobutanil there does not appear to be an extra sensitivity for pre- or post-natal effects.

Based on the above, HED concludes that reliable data support use of a 100-fold margin of exposure/uncertainty factor, rather than the standard 1000-fold margin/factor, to protect infants and children.

4. Acute Aggregate Risk for Infants and Children.

This risk assessment is not required as the HAZID SARC did not recommend an acute dietary risk endpoint.

5. Chronic Aggregate Risk for Infants and Children.

Using the partially refined exposure assumptions described above, HED has concluded that the percent of the RfD that will be utilized by dietary (food only) exposure to residues of myclobutanil ranges from 25% for nursing infants (<1 year old) up to 75% for non-nursing infants (<1 year old). The percent of the RfD that will be used by the food and water exposure for children (1-6 years old) is 62% (i.e., 46% from food + 16% from water).

6. Short- and Intermediate-Term Aggregate Risk for Infants and Children.

Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses. Although short-term exposure scenarios may be present, based on the lack of acute toxicological endpoints and the low percent of RfD occupied, in the best scientific judgement of HED, aggregate short- and intermediate-term risk will not exceed HED's level of concern. Additionally, HED notes that there are no indoor residential uses of myclobutanil; thus, indoor residential exposure is expected to be minimal.

DETERMINATION OF SAFETY TO OCCUPATIONALLY EXPOSED WORKERS

1. Acute data for this formulation were available to RAB1 in conjunction with a recent import tolerance petition for bananas (PP#2E04141). The proposed work clothing and personal protective equipment (PPE) appearing on the label for Nova 40W in water-soluble pouches include long-sleeved shirt and long pants, waterproof gloves, shoes plus socks, protective eyewear and chemical-resistant headgear for overhead exposure; These work clothing and PPE are in compliance with the Worker Protection Standard (WPS).

2. Acute data for the technical are also available to RAB1. According to the recent import tolerance petition for bananas (PP#2E04141), myclobutanil is a category III for acute oral and acute dermal; category IV for primary dermal irritation and acute inhalation; and category I for primary eye irritation. Based on these values, the restricted entry interval (REI) should be 48 hours to be in compliance with the WPS. However, an REI of 24

hours appears on the label. Additional data may have been submitted to support a 24 hour REI for this chemical. **RD should insure that the appropriate REI statement appears on the label.**

3. Occupational exposure assumptions and estimates are summarized in Tables 1 and 2, respectively.

Worker exposure estimates are based on surrogate data from the Pesticide Handlers Exposure Database (PHED) and/or the PHED Surrogate Exposure Guide (May 1997) with the worker wearing a single layer of clothing plus gloves. It should be noted that the mixer/loader estimate used a medium confidence "open bag" scenario which would over-estimate exposure for myclobutanil in water-soluble pouches.

4. Using these exposure assumptions, HED has concluded that the MOEs that will result from the handling and application of myclobutanil by workers range from 3,800 for ground mixer/loader to 45,000 for ground applicator. These MOEs do not exceed HED's level of concern for occupationally exposed workers.

OTHER CONSIDERATIONS

Metabolism in Plants and Animals

1. The nature of the residue in strawberries is adequately understood. The residues of concern in strawberries are myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound), as specified in 40 CFR 180.443(a).

Analytical Enforcement Methodology

2. An adequate enforcement method (Rohm and Haas Method 34S-88-10, MRID# 408033-02) is available to enforce the proposed tolerance on strawberries. Quantitation is by GLC using a nitrogen/phosphorus detector for myclobutanil and an electron capture detector (Ni⁶³) for residues measured as the alcohol metabolite [alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile].

Magnitude of the Residues

3. Combined residues of myclobutanil and its alcohol metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) are not expected to exceed 0.5 ppm in/on strawberries. A time-limited tolerance should be established at this level.

4. Secondary residues are not expected in animal commodities as no feed items are associated with this Section 18 use.

Rotational Crop Restrictions

5. Information concerning the likelihood of residues in rotational crops is not available for myclobutanil. Since strawberry fields may be rotated, **HED concludes that the following restriction should be added to the label for the requested Section 18 on strawberries: Myclobutanil treated fields can be rotated at any time to crops which are included on a myclobutanil label. All other crops may be planted one year following applications of myclobutanil.**

International Residue Limits

6. There are no Codex, Canadian or Mexican residue limits established for myclobutanil and its metabolites on strawberries. Therefore, no compatibility problems exist for the proposed tolerance on strawberries.

SUPPLEMENTAL INFORMATION

OCCUPATIONAL EXPOSURE

Table 4. Occupational Exposure Assumptions	
PARAMETER	ASSUMPTION
Pesticide Handlers Exposure Database (PHED), Version 1.1, Unit of Exposure From PHED Surrogate Exposure Guide (May 1997)	Mixer/Loader (wetable powder, open bag, single layer clothing plus gloves): Dermal = 167.5 $\mu\text{g/lb ai}$ handled. <i>Medium Confidence Run.</i>
	Applicator (groundboom, open cab, single layer clothing plus gloves): Dermal = 14.0 $\mu\text{g/lb ai}$ applied. <i>Medium Confidence Run.</i>
Percent Absorption	Dermal: <u>NA</u> (based on dermal toxicity study)
Application Type	Ground
Minimum Finish Spray	Ground: <u>20</u> gal/A
Maximum Application Rate	<u>0.125</u> lb ai/A
Maximum Applications Per Year	<u>6</u>
Duration of Occupational Exposure	Short-Term (one day to one week)
Acres Treated/Day (Y. NG,BEAD)	Ground: <u>89</u> acres
Average Farm Size (1992 Ag Census)	Based on Hillsborough county, FL <u>25</u> acres
Worker Weight	<u>70</u> kg (based on Tox endpoint)
Number of Farms Treated by PCO (Professional Chemical Operator)	Ground: 2

Table 5. Occupational Exposure and Risk Assessment ^a		
Worker	Average Daily Dermal Dose ^b ($\mu\text{g/kg/day}$)	Short-Term MOE ^c
Ground Mixer/Loader	26.6	3,800
Ground Applicator	2.2	45,000

^a MOEs are expressed to two significant figures.

^b Average Daily Dose (ADD) = PHED dermal unit exposure x application rate x acres treated/day \div kg body weight. The TES did not identify an inhalation tox endpoint.

^c Short-Term Occupational Dermal Exposure MOE = NOEL/ADD (where NOEL = 100 mg/kg/day).

DIETARY EXPOSURE

NOTE: The submitted Section 18 label states that a maximum of 0.75 lb ai/A/crop (30 ozs product/A/crop) may be applied. This should be modified to state that a maximum of 0.75 lb ai/A/**YEAR** (30 ozs product/A/**YEAR**) can be applied.

Table 6. Residue Consideration Summary Table		
PARAMETER	PROPOSED USE	RESIDUE DATA
CHEMICAL	Myclobutanil	Myclobutanil
FORMULATION	Nova 40W Agricultural Fungicide in Water-Soluble Pouches (Rohm and Has, EPA Reg. #707-221)	Rally 40W/Nova 40W
CROP	Strawberries	Strawberries
TYPE APPLICATION	Ground - broadcast	Ground - broadcast
# APPLICATIONS	Not specified	6
TIMING	Make applications 14 to 21 days apart when disease first appears.	Post-emergence, at 6-22 day intervals, PHIs ranged from 0 to 7 days
RATE/APPLICATION	0.0625 - 0.125 lb ai/A (2.5 - 5.0 oz product/A)	0.031 - 0.125 lb ai/A
RATE/YEAR or SEASON	0.75 lb ai/A/crop (30 ozs product/A/crop)	0.75 lb ai/A/crop
MAXIMUM RESIDUE		0.31 ppm myclobutanil and <0.02 ppm for the alcohol metabolite
RESTRICTIONS	3 day PHI	
RESIDUE DATA SOURCE		IR-4 (PP#4E4302)
PERFORMING LAB		Del Monte Research Center, Walnut Creek, CA

ADDITIONAL INFORMATION

Animal Feedstuffs Considerations. Not applicable.

Processed By-Products. Not applicable.

Progress Toward Registration. IR-4 submitted a petition for a Section 3 registration on strawberries in 1993. Rohm and Haas Company is now conducting rotational crop studies. The testing is expected to be completed in 1998. (Source: the specific exemption request for strawberries in Florida dated 9/11/97)

Reregistration Status. Myclobutanil is not a reregistration lists chemical.

Attachment 1: DRES Run: Chronic: W. Cutchin, 6/23/97

cc with Attachment 1: N. Dodd, W. Dykstra, B. Tarplee, M. Lamont, RAB 1, Section 18 File

cc without Attachment 1: OREB (128857), Caswell File
RDI:RAB 1: 12/8/97

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 06/23/97

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723A CAS No. 88671-89-0 A.I. CODE: 120857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinog- enicity in rats or mice.	ADI UF --->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	MED reviewed 01/27/88 EPA verified 02/25/88 MNO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RfD	DIFFERENCE AS PERCENT OF RfD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**			ARC	XRfD
U.S. POPULATION - 48 STATES	0.004139	0.005952	23.807128	7.251904	0.004255	17.01972
U.S. POPULATION - SPRING SEASON	0.003914	0.005624	22.494828	6.837964	0.004008	16.03145
U.S. POPULATION - SUMMER SEASON	0.004530	0.006333	25.331996	7.213420	0.004314	17.25707
U.S. POPULATION - FALL SEASON	0.004089	0.005955	23.818896	7.463276	0.004366	17.46522
U.S. POPULATION - WINTER SEASON	0.004001	0.005873	23.493788	7.490208	0.004308	17.23102
NORTHEAST REGION	0.004507	0.006339	25.355912	7.329784	0.004539	18.15719
NORTH CENTRAL REGION	0.004196	0.006004	24.017028	7.232888	0.004368	17.47235
SOUTHERN REGION	0.003340	0.004922	19.689516	6.330536	0.003577	14.30908
WESTERN REGION	0.004914	0.007106	28.423816	8.769604	0.004848	19.39143
HISPANICS	0.004795	0.007380	29.518340	10.336920	0.005049	20.19736
NON-HISPANIC WHITES	0.004215	0.006060	24.239212	7.379800	0.004324	17.29743
NON-HISPANIC BLACKS	0.003272	0.004477	17.907284	4.818884	0.003363	13.45043
NON-HISPANIC OTHERS	0.004299	0.006425	25.700248	8.502744	0.004425	17.70064
NURSING INFANTS (< 1 YEAR OLD)	0.009543	0.014037	56.147932	17.976872	0.006359	25.43698
NON-NURSING INFANTS (< 1 YEAR OLD)	0.024640	0.030308	121.233972	22.674608	0.018836	75.34262
FEMALES (13+ YEARS, PREGNANT)	0.002968	0.004244	16.985764	5.115344	0.003124	12.49575
FEMALES 13+ YEARS, NURSING	0.003798	0.005409	21.635288	6.442704	0.003932	15.72664
CHILDREN (1-6 YEARS OLD)	0.011418	0.016220	64.881224	19.210812	0.011492	45.96947
CHILDREN (7-12 YEARS OLD)	0.006439	0.009123	36.491708	10.736580	0.006910	27.63822
MALES (13-19 YEARS OLD)	0.003676	0.005310	21.239784	6.536892	0.004246	16.98476
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.003069	0.004419	17.674952	5.398156	0.003412	13.64812
MALES (20 YEARS AND OLDER)	0.002442	0.003683	14.732932	4.963320	0.002640	10.55916
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.002474	0.003682	14.726744	4.832204	0.002517	10.06981

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.

ATTACHMENT I

TOLERANCE ASSESSMENT SUMMARY FOR Myclobutanil (Systane/Rally) DATE: 06/23/97
 USING ANTICIPATED RESIDUES
 CASWELL #723K

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.003237	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	12.967	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000828	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	3.313	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.004065	MG/KG/DAY
THE NEW ARC WILL OCCUPY	16.261	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000190	MG/KG/DAY
THIS ARC WILL OCCUPY	0.759	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.004255	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	17.020	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.017361	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	69.444	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000545	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	2.178	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.017906	MG/KG/DAY
THE NEW ARC WILL OCCUPY	71.622	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000930	MG/KG/DAY
THIS ARC WILL OCCUPY	3.721	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.018834	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	75.343	% OF THE ADI.

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 723K

DATE: 06/23/97

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Relly) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinog- enicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	NED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
01014AA	GRAPES-FRESH	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014AA	GRAPES-FRESH	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014AA	GRAPES-FRESH	31 COOKED-FRESH OR CANNED	7F3476	P 1.000000	1.000000		79.00	0.790000
01014DA	GRAPES-RAISINS	10 RAW-FRESH OR NFS	7N5524	P 10.000000	10.000000C		79.00	7.900000
01014DA	GRAPES-RAISINS	21 COOKED-NFS	7N5524	P 10.000000	10.000000C		79.00	7.900000
01014DA	GRAPES-RAISINS	22 COOKED-FRESH-BAKED	7N5524	P 10.000000	10.000000C		79.00	7.900000
01014JA	GRAPES-JUICE	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014JA	GRAPES-JUICE	15 RAW-FRESH OR CANNED	7F3476	P 1.000000	1.000000		79.00	0.790000
01014JA	GRAPES-JUICE	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01016AA	STRAWBERRIES	10 RAW-FRESH OR NFS	97FL001	P 0.500000	0.500000		100.00	0.500000
01016AA	STRAWBERRIES	21 COOKED-NFS	97FL001	P 0.500000	0.500000		100.00	0.500000
01016AA	STRAWBERRIES	70 RAW-FROZEN	97FL001	P 0.500000	0.500000		100.00	0.500000
03001AA	ALMONDS	10 RAW-FRESH OR NFS	0F3876	P 0.100000	0.100000		1.00	0.001000
03001AA	ALMONDS	21 COOKED-NFS	0F3876	P 0.100000	0.100000		1.00	0.001000
03001AA	ALMONDS	22 COOKED-FRESH-BAKED	0F3876	P 0.100000	0.100000		1.00	0.001000
04001AA	APPLES-FRESH	10 RAW-FRESH OR NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	21 COOKED-NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	31 COOKED-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	10 RAW-FRESH OR NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	22 COOKED-FRESH-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001JA	APPLES-JUICE	15 RAW-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001JA	APPLES-JUICE	31 COOKED-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04002AA	CRABAPPLES	00 NOT SPECIFIED (NO CONSUMPTION)	9F3812	A 0.500000	0.500000		100.00	0.500000
04003AA	PEARS-FRESH	10 RAW-FRESH OR NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	31 COOKED-FRESH OR CANNED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	51 COOKED-CANNED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003DA	PEARS-DRIED	10 RAW-FRESH OR NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04003DA	PEARS-DRIED	21 COOKED-NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04004AA	QUINCES	00 NOT SPECIFIED (NO CONSUMPTION)	9F3812	A 0.500000	0.500000		100.00	0.500000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001AA	APRICOTS-FRESH	21 COOKED-NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001AA	APRICOTS-FRESH	31 COOKED-FRESH OR CANNED	1F3954	P 2.000000	2.000000		1.00	0.020000
05001DA	APRICOTS-DRIED	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001DA	APRICOTS-DRIED	22 COOKED-FRESH-BAKED	1F3954	P 2.000000	2.000000		1.00	0.020000
05002AA	CHERRIES-FRESH	10 RAW-FRESH OR NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	21 COOKED-NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	31 COOKED-FRESH OR CANNED	2F4116	P 5.000000	5.000000		47.00	2.350000

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 723K

DATE: 06/23/97

PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myoclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	NED reviewed 01/27/88 EPA verified 02/25/88 MNO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
05002AA	CHERRIES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	2F4116	P 5.000000	5.000000		47.00	2.350000
05002DA	CHERRIES-DRIED	00 NOT SPECIFIED (NO CONSUMPTION)	2F4116	P 5.000000	5.000000		47.00	2.350000
05002JA	CHERRIES-JUICE	15 RAW-FRESH OR CANNED	2F4116	P 5.000000	5.000000		47.00	2.350000
05002JA	CHERRIES-JUICE	21 COOKED-NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05003AA	NECTARINES	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		21.00	0.420000
05004AA	PEACHES-FRESH	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	21 COOKED-NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	31 COOKED-FRESH OR CANNED	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	51 COOKED-CANNED	9F3811	P 2.000000	2.000000		22.00	0.440000
05004DA	PEACHES-DRIED	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004DA	PEACHES-DRIED	21 COOKED-NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05005AA	PLUMS-FRESH	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		3.00	0.060000
05005AA	PLUMS-FRESH	31 COOKED-FRESH OR CANNED	1F3954	P 2.000000	2.000000		3.00	0.060000
05005DA	PLUMS-PRUNES	10 RAW-FRESH OR NFS	1N5608	P 8.000000	8.000000C		3.00	0.240000
05005DA	PLUMS-PRUNES	21 COOKED-NFS	1N5608	P 8.000000	8.000000C		3.00	0.240000
05005DA	PLUMS-PRUNES	31 COOKED-FRESH OR CANNED	1N5608	P 8.000000	8.000000C		3.00	0.240000
05005JA	PRUNE-JUICE	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		3.00	0.060000
05005JA	PRUNE-JUICE	62 COOKED-FRESH OR FROZEN-BAKED	1F3954	P 2.000000	2.000000		3.00	0.060000
06002AA	BANANAS-UNSPEC	22 COOKED-FRESH-BAKED	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	10 RAW-FRESH OR NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	31 COOKED-FRESH OR CANNED	2E04141	A 4.000000	0.800000		100.00	0.800000
06002DA	BANANAS-DRIED	10 RAW-FRESH OR NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002DA	BANANAS-DRIED	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	23 COOKED-FRESH-BOILED	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	25 COOKED-FRESH-FRIED	2E04141	A 4.000000	0.800000		100.00	0.800000
10002AA	CANTALOUPE-UNSP	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10002AB	CANTALOUPE-PULP	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10002AB	CANTALOUPE-PULP	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10003AA	CASABAS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10004AA	CRENSHAW	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10005AA	HONEYDEW MELONS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10007AA	PERSIAN MELONS	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10008AA	WATERMELON	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10008AA	WATERMELON	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	11 RAW-FRESH-PICKLED,CORNEED,OR CURED	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 723K

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinog- enicity in rats or mice.	ADI UF-->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
10011AA	PUMPKIN	22 COOKED-FRESH-BAKED	SECT18	P 0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	62 COOKED-FRESH OR FROZEN-BAKED	SECT18	P 0.300000	0.300000		100.00	0.300000
10013AA	SQUASH-SUMMER	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10013AA	SQUASH-SUMMER	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	31 COOKED-FRESH OR CANNED	SECT18	P 0.300000	0.300000		100.00	0.300000
10017AA	BITTER MELON	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10020AA	TOMELGOURD	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
11003AA	PEPPERS,SWEET	10 RAW-FRESH OR NFS	97CA036	P 1.000000	1.000000		100.00	1.000000
11003AA	PEPPERS,SWEET	21 COOKED-NFS	97CA036	P 1.000000	1.000000		100.00	1.000000
11003AB	CHILI PEPPERS	00 NOT SPECIFIED (NO CONSUMPTION)	97CA036	P 1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	10 RAW-FRESH OR NFS	97CA036	P 1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	21 COOKED-NFS	97CA036	P 1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	51 COOKED-CANNED	97CA036	P 1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	10 RAW-FRESH OR NFS	97CA036	P 1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	21 COOKED-NFS	97CA036	P 1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	31 COOKED-FRESH OR CANNED	97CA036	P 1.000000	1.000000		100.00	1.000000
11005AA	TOMATOES-WHOLE	10 RAW-FRESH OR NFS	97CA042	N 0.300000	0.300000		100.00	0.300000
11005AA	TOMATOES-WHOLE	21 COOKED-NFS	97CA042	N 0.300000	0.300000		100.00	0.300000
11005AA	TOMATOES-WHOLE	31 COOKED-FRESH OR CANNED	97CA042	N 0.300000	0.300000		100.00	0.300000
11005JA	TOMATOES-JUICE	10 RAW-FRESH OR NFS	97CA042	N 0.300000	0.300000		100.00	0.300000
11005JA	TOMATOES-JUICE	21 COOKED-NFS	97CA042	N 0.300000	0.300000		100.00	0.300000
11005RA	TOMATOES-PUREE	10 RAW-FRESH OR NFS	97CA042	N 0.600000	0.600000		100.00	0.600000
11005RA	TOMATOES-PUREE	21 COOKED-NFS	97CA042	N 0.600000	0.600000		100.00	0.600000
11005RA	TOMATOES-PUREE	31 COOKED-FRESH OR CANNED	97CA042	N 0.600000	0.600000		100.00	0.600000
11005RA	TOMATOES-PUREE	32 COOKED-FRESH OR CANNED-BAKED	97CA042	N 0.600000	0.600000		100.00	0.600000
11005RA	TOMATOES-PUREE	51 COOKED-CANNED	97CA042	N 0.600000	0.600000		100.00	0.600000
11005TA	TOMATOES-PASTE	21 COOKED-NFS	97CA042	N 1.200000	1.200000		100.00	1.200000
11005TA	TOMATOES-PASTE	22 COOKED-FRESH-BAKED	97CA042	N 1.200000	1.200000		100.00	1.200000
11005TA	TOMATOES-PASTE	31 COOKED-FRESH OR CANNED	97CA042	N 1.200000	1.200000		100.00	1.200000
11005UA	TOMATOES-CATSUP	21 COOKED-NFS	97CA042	N 0.600000	0.600000		100.00	0.600000
16002AA	ASPARAGUS	21 COOKED-NFS	97CA026	P 0.010000	0.010000		100.00	0.010000
16002AA	ASPARAGUS	23 COOKED-FRESH-BOILED	97CA026	P 0.010000	0.010000		100.00	0.010000
270030A	COTTONSEED-OIL	18 PROCESSED OIL	4F4317	P 0.020000	0.020000		1.00	0.000200
270030A	COTTONSEED-MEAL	18 PROCESSED OIL	4F4317	P 0.020000	0.020000		1.00	0.000200
28080AA	PEPPERMINT	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	P 2.500000	2.500000		100.00	2.500000
280800A	PEPPERMINT-OIL	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	P 2.500000	2.500000		100.00	2.500000
28081AA	SPEARMINT	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	P 2.500000	2.500000		100.00	2.500000
280810A	SPEARMINT-OIL	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	P 2.500000	2.500000		100.00	2.500000

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Mycllobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinog- enicity in rats or mice.	ADI UF --->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	NED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AA STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
43058AA	WINE AND SHERRY	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
43058AA	WINE AND SHERRY	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
500000B	MILK-NON-FAT SOL	10 RAW-FRESH OR NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
500000B	MILK-NON-FAT SOL	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
500000B	MILK-NON-FAT SOL	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	10 RAW-FRESH OR NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
50000SA	MILK SLUG (LACT)	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000SA	MILK SLUG (LACT)	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BA	BEEF-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BA	BEEF-MEAT BYP	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BB	BEEF-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BB	BEEF-OTH ORGAN	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001DA	BEEF-DRIED	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001FA	BEEF-FAT	10 RAW-FRESH OR NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	22 COOKED-FRESH-BAKED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	24 COOKED-FRESH-BROILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001KA	BEEF-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001LA	BEEF-LIVER	25 COOKED-FRESH-FRIED	0F3876	P 1.000000	1.000000		100.00	1.000000
53001LA	BEEF-LIVER	31 COOKED-FRESH OR CANNED	0F3876	P 1.000000	1.000000		100.00	1.000000
53001MA	BEEF-LEAN	10 RAW-FRESH OR NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53002BA	GOAT-MEAT BYP	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002BB	GOAT-OTH ORGAN	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002FA	GOAT-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53002FA	GOAT-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53002KA	GOAT-KIDNEY	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002LA	GOAT-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53002MA	GOAT-LEAN	23 COOKED-FRESH-BOILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53002MA	GOAT-LEAN	25 COOKED-FRESH-FRIED	0F3876	P 0.100000	0.100000		100.00	0.100000
53003AA	HORSE	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53005BA	SHEEP-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005BB	SHEEP-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 723K

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinog- enicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AN STATISTIC TYPE	% CROP TREATED	RES. VALUE USED (IN TAS RUN (ppm))
53005FA	SHEEP-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53005KA	SHEEP-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005LA	SHEEP-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53005MA	SHEEP-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53005NA	SHEEP-LEAN	31 COOKED-FRESH OR CANNED	0F3876	P 0.100000	0.100000		100.00	0.100000
53006BA	PORK-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006BB	PORK-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006BB	PORK-OTH ORGAN	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	0F3876	P 0.200000	0.200000		100.00	0.200000
53006FA	PORK-FAT	10 RAW-FRESH OR NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006KA	PORK-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006LA	PORK-LIVER	21 COOKED-NFS	0F3876	P 1.000000	1.000000		100.00	1.000000
53006LA	PORK-LIVER	25 COOKED-FRESH-FRIED	0F3876	P 1.000000	1.000000		100.00	1.000000
53006MA	PORK-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53006MA	PORK-LEAN	25 COOKED-FRESH-FRIED	0F3876	P 0.100000	0.100000		100.00	0.100000
53006MA	PORK-LEAN	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	0F3876	P 0.100000	0.100000		100.00	0.100000
55008BA	TURKEY-BYP	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008BA	TURKEY-BYP	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008LA	TURKEY ORGAN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008LA	TURKEY ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MB	TURKEY+SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MB	TURKEY+SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MC	TURKEY-UNSPEC	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55013BA	POULTRY, OTH-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	7F3476	P 0.020000	0.020000		100.00	0.020000
55013LA	POULTRY, ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55013MA	POULTRY, OTHER	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	23 COOKED-FRESH-BOILED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	22 COOKED-FRESH BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myxobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinog- enicity in rats or mice.	ADI UF-->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
55014AB	EGGS-WHITE ONLY	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	81 COOKED-FROZEN	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015BA	CHICKEN-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	53 COOKED-CANNED-BOILED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MB	CHICKEN+SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MB	CHICKEN+SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000



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